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| F. # 2018R02044 | |
| UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORKX | |
| UNITED STATES OF AMERICA | FILED UNDER SEAL |
| - against - | AFFIDAVIT AND COMPLAINT IN SUPPORT |
| JASON VALE and BARBARA VALE, | OF AN ARREST WARRANT |
| Defendants. | 19-MJ-969 (18 U.S.C. §§ 2, 402, 542 and 554) |
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EASTERN DISTRICT OF NEW YORK, SS:

ANTHONY P. RUFFINI, being duly sworn, deposes and states that he is a Special Agent with the United States Food and Drug Administration, duly appointed according to law and acting as such.

In or about and between 2013, and October 2019, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendants JASON VALE and BARBARA VALE, together and with others, did knowingly and willfully disobey the lawful order of the United States District Court for the Eastern District of New York ("the Court"), to wit: the November 17, 2000 Consent Decree of Permanent Injunction entered by the Honorable John Gleeson in <u>United States v. Christian Bros. Contracting Corp.</u>, a corporation, and Jason Vale, an individual, Civil Action No. 99-CV-7683.

(Title 18, United States Code, Sections 2 and 402)

In or about & between November 28, 2016, and December 3, 2016, within the Eastern District of New York, defendant BARBARA VALE, together with others, did fraudulently send from the United States merchandise contrary to the laws and regulations of the United States.

(Title 18, United States Code, Sections 2 and 554)

On or about March 2, 2019, within the Eastern District of New York, defendant JASON VALE, together with others, did knowingly introduce into the commerce of United States imported merchandise by means of false statements, and did procure the making of such false statements.

(Title 18, United States Code, Sections 2 and 542)

The source of your deponent's information and the grounds for his belief are as follows:¹

1. I am a Special Agent with the Food and Drug Administration's Office of Criminal Investigations ("FDA") and have been since April 2018. Prior to that, I was a Special Agent with the United States Department of Agriculture, Office of Inspector General, from February 2015 through 2018. During my time as a federal law enforcement officer, I have personally participated in numerous investigations and arrests, the debriefing of witnesses and the execution of numerous search warrants related to various types of criminal activity including, among others, mail fraud and violations of the Food, Drug and Cosmetic Act ("FDCA"). I am familiar with the facts and circumstances set forth below from: (a) my

Because the purpose of this Complaint is to set forth only those facts necessary to establish probable cause to arrest, I have not described all the relevant facts and circumstances of which I am aware.

participation in the investigation; (b) my review of the investigative file and reports of other law enforcement officers involved in the investigation; and (c) my review of bank records, telephone records, social media accounts and other sources of information.

PROBABLE CAUSE

A. Background Regarding Sale of Laetrile and Similar Products

2. Based on my investigation, I know that there is an active market for products that have not been approved by the U.S. Food and Drug Administration ("FDA"), but that sellers nonetheless market as being able to treat and cure diseases, including cancer. One of these products is amygdalin. Amygdalin is a glucoside found in the kernel or seeds of most fruits and is frequently referred to as "Laetrile" or "Vitamin B-17." While some people believe that Laetrile can treat and control cancer, the FDA does not support this claim. Additionally, there are no published clinical studies supporting the claim that Laetrile is safe or effective. Thus FDA does not support the use of Laetrile for the treatment of cancer. Moreover, the medical community has found that cancer patients who nonetheless utilize Laetrile often forgo conventional therapies to their detriment, thus presenting a health risk. It is a violation of the Food Drug and Cosmetic Act to promote unapproved and misbranded drugs as a cure for any disease, including cancer.

B. <u>Legal Proceedings</u>

3. In 1999, the government filed a civil action in the Eastern District of New York against JASON VALE, an individual, and his company Christian Brothers Contracting Corporation, a corporation, alleging, inter alia, that they were distributing Laetrile as a cure for cancer and seeking, inter alia, that they be permanent enjoined from selling or promoting Laetrile as a cure for cancer in the future (the "Civil Action"). (United States v. Christian

Bros. Contracting Corp., a corporation, and Jason Vale, an individual, Civil Action No. 99-CV-7683.)

- 4. On April 20, 2000, JASON VALE, Christian Bros. and their attorneys appeared at the hearing on the government's motion for a preliminary injunction. At that time they offered no evidence or legal arguments to suggest that the government was not entitled to a preliminary injunction; to the contrary, they consented to the issuance of a preliminary injunction.
- 5. On November 17, 2000, the Honorable John Gleeson approved a Consent Decree of Permanent Injunction (the "INJUNCTION") permanently restraining and enjoining JASON VALE, Christian Bros. Contracting Corp. "and each and all of their agents, representatives, employees, successors and assigns, and any and all persons in active concert or participation with any of them" from *inter alia*:

Introducing or delivering for introduction into interstate commerce, holding or sale after shipment in interstate commerce, manufacturing, processing, packing, labeling, promoting in violation of the FDC Act, or distributing amygdalin, laetrile, "Vitamin B-17", apricot seeds, any similar product containing or purporting to contain amygdalin, laetrile, "Vitamin B-17", or apricot seeds, or any drug product that is a new drug as defined in 21 USC 321 (p)...."

- 6. Despite entering into the INJUNCTION, JASON VALE and Christian Bros. Contracting Corp. continued to sell amygdalin, laetrile, Vitamin B-17, apricot seeds and similar products (the "Enjoined Substances") in violation of the INJUNCTION.
- 7. On April 16, 2002, based upon the affidavit of a special agent of the FDA, the district court initiated a criminal contempt prosecution against JASON VALE by issuing an order to show cause. The order to show cause charged JASON VALE with four counts of criminal contempt in violation of 18 U.S.C. § 401(3): (1) that, with the intent to

deceive the FDA, the district court and his customers, JASON VALE labeled, packed and distributed laetrile in violation of the preliminary injunction in the Civil Action; (2) that, with the intent to deceive the FDA, the district court and his customers, JASON VALE labeled, packed and distributed laetrile in violation of the permanent injunction in the Civil Action (Count Two); (3) that JASON VALE promoted laetrile as a cure for cancer over the Internet in violation of the preliminary injunction in the Civil Action (Count Three); and (4) that JASON VALE promoted laetrile in violation of the FDCA as a cure for cancer over the Internet in violation of the permanent injunction in the Civil Action (Count Four). (United States v. Vale, No. 02 CR 466.)

- 8. On July 21, 2003, JASON VALE was convicted after a trial before Judge Gleeson of Counts 1-3 of criminal contempt, which stemmed from his violations of the express terms of the INJUNCTION issued by Judge Gleeson.² (No. 02 CR 466, ECF No. 83.) Thereafter, Judge Gleeson sentenced JASON VALE to 63 months' incarceration. (ECF No. 128.) In 2005, the Second Circuit affirmed Jason Vale's convictions. <u>United States v. Vale</u>, 140 F. App'x. 302 (2d. Cir. 2005).
- 9. Notably, BARBARA VALE knew of the charges against JASON VALE and attended the trial. In addition, there was testimony during the trial that BARBARA VALE answered the phone for JASON VALE's business and participated in the sale of the Enjoined Substances.

² The United States voluntarily dismissed Count 4 on July 16, 2019, during the trial.

10. On February 2, 2005, in response to a <u>pro se</u> motion for "clarification" of the INJUNCTION filed by JASON VALE, Judge Gleeson observed:

I find the application troubling. First, Vale has demonstrated great familiarity (but not great compliance) with the statutes and regulations at issue in this case. He can read the relevant provisions of the FDC Act himself for a reminder of the conduct he agreed would be prohibited by the consent decree. Second, given the extensive, lucrative and fraudulent conduct that gave rise to Vale's contempt conviction, the last endeavor he should be planning is the promotion of laetrile products in <u>any</u> way.

(No. 99 CV 7683, ECF No. 40.)

Judge Gleeson ultimately denied the motion and did not issue any clarification of the INJUNCTION.

C. Use of WEBSITE to Sell Laetrile

- 11. Since at least January 2013, until the present, JASON VALE and BARBARA VALE (collectively, the "VALES") have been operating an online business through a website called "Apricotsfromgod.info" (the "WEBSITE"), from which consumers may purchase various products including Enjoined Substances. The VALES also operate other websites which automatically redirect visitors to the WEBSITE.
- 12. As recently as June 10, 2019, statements on the WEBSITE provide in relevant part:

The Answer to Cancer is known! Just a few seeds per day. Edgar Cayce claimed over 40 years ago that just 2 bitter almonds a day and one would never see cancer in their lifetime.... Each one of the above diseases killed many, millions in some cases and took decades upon decades before it just became common knowledge as to the cures. In no case did Big Pharma make an announcement as to these cures until, like I said, it just became common knowledge. Bitter almonds are no longer available in the U.S. Apricot seeds contain the same vitamin nutrient

sometimes called vitamin B17, nitrilosides or amydgalin. At one time Laetrile was the commercial name for these nitrilosides.

* * * * *

THE SEED. Tens of thousands know the answer to cancer, and do not fear the disease, myself included.

* * * * *

A while ago, a man from my church, Bill DePap, gave me a video tape called 'World Without Cancer', by G. Edward Griffin. It told the truth of a vitamin that contains cyanide and that it's found in seeds, certain grains, grasses and minutely in beans and meats . . For six years I've been researching the information contained in the tape as well as using it to treat my kidney cancer. It's all true.

* * * * *

Below are news reports of some studies showing that Cyanide kills cancer. (The apricot seeds have Cyanide in them but even the good guys have to make money so they can't tell you to just eat apricot seeds and some of the other 1200 food with cyanide in them.)

13. The website also contains an excerpt from a speech given by Ernest Krebs, Jr. regarding the use of B17 in treating cancer. It states in relevant part:

It is certainly a pleasure to be here at the Second Annual Convention of the Cancer Control Society-an outgrowth, as you know, of the International Association of Cancer Victims and Friends. As I look back through the years marketing the emergence of these two fine Societies, I can recall the number of miraculous victories we have had in those intervening years; that it is as true today as it was eleven years ago that Laetrile, Vitamin B17, is the first and last final hope in the prophylasis in therapy of cancer in man and animals. The reason for this is that Laetrile is a vitamin. It is the 17th of the B vitamins.

We hear a great deal about its use in terminal cancer, but the time to start with vitamin B17 is now before the disease become [sic] clinical. ...

14. Additionally, under the "Cancer" section of the WEBSITE, there is information regarding the history of natural foods that purportedly proves that they are

capable of treating certain diseases. In this section, the WEBSITE advocates that Vitamin B17 is an effective treatment for cancer. It states in relevant part: "Nothing has come about to do anything except to make more obvious the fact that Laetrile, Vitamin B17 is the answer to cancer."

15. On October 18, 2019, I again visited the WEBSITE and confirmed that it is still operational, and continues to tout the health benefits of the Enjoined Substances as well as offer them for sale. These statements include:

THE ANSWER TO CANCER IS KNOWN

If I sell orange juice for cancer, I am now selling a drug as defined under 21 U.S.C. 352. The law has been formed over years and years of court cases, each one adding to the lock that doctors have over treating disease. There is a list of "diseases" that only doctors are allowed to treat. This list includes CANCER, ARTHRITIS, DIABETES, HEART DISEASE, and hundreds of other "names" of ailments which the establishment has secured patents on. They own the words of all the diseases and the words TREAT, CURE, MITIGATE etc. If I sell you string beans for you diabetes, I am now selling an illegal unapproved drug. No matter how many people we CURED with apricot seeds, the vitamin B-17 that is found in them and some other aids, it does not matter. As a matter of fact, we have had over a 90 percent success rate with the apricot seeds and other aids, but our records do not matter.

D. Undercover Purchases From The WEBSITE

16. In 2018 and 2019, the Food and Drug Administration ("FDA") effected several undercover purchases through the WEBSITE. The financial aspect of the WEBSITE transactions were conducted through an account operated by Paypal, Inc. (the "PAYPAL ACCOUNT"). Paypal, Inc. records indicate that Barbara Vale is the registered owner of the PAYPAL ACCOUNT. Further, the PAYPAL ACCOUNT is associated with email address "babsie214@aol.com" (the "BARBARA VALE EMAIL ACCOUNT"). A search warrant of the BARBARA VALE EMAIL ACCOUNT was authorized by the Honorable Steven M. Gold

on May 2, 2019. An execution of that search warrant revealed that the subscriber of the BARBARA VALE EMAIL ACCOUNT was "Barbara Vale."

- 17. Transaction logs from Paypal, Inc. contain information such as "Item ID" and "Item Title." Paypal transaction logs for the PAYPAL ACCOUNT from January 2013 to September 22, 2019 indicate that the majority of sales made through that account are for the Enjoined Substances, including apricot seeds (e.g., "Apricot Seeds 1 Pound," "Vitamin B17, 500 mg Capsules," "DMSO 8oz. bottle," "SuperZyme").
- 18. Based on a review of records received from Paypal Inc., payments made to the VALE PAYPAL ACCOUNT for the purchase of Enjoined Substances, from January 2013 through September 22, 2019, have totaled more than \$850,000.
- 19. On March 1, 2019, the FDA placed an undercover buy through the WEBSITE for "3lbs Apricot Seeds/3 bottles Vit B-17 (500mg) 100 ea. & DVD" (the "ORDER"). The ORDER total was \$259.00 plus \$27.75 in shipping costs. The ORDER was shipped through the United States Postal Service ("USPS") with a Click-N-Ship³ label linked to a specific Click-N-Ship account number (the "Click-N-Ship Account"). The entity associated with the Click-N-Ship Account is "Christian Brothers," the email address associated with the Click-N-Ship Account is the BARBARA VALE EMAIL ACCOUNT and the physical address associated with the Click-N-Ship Account is 82-51 234th Street, Queens, New York 11427 (the "234th Street Address"), BARBARA VALE's residence. The email confirmation for the ORDER was sent from Paypal, Inc. and indicated that the \$286.75 payment was sent

³ Click-N-Ship is a service by USPS that allows customers to print out their own postage and labels, with USPS bar codes, and schedule USPS pickups.

to the merchant "health clearing house (babsie214@aol.com);" i.e., the BARBARA VALE EMAIL ACCOUNT.

E. Execution of the BARBARA VALE EMAIL ACCOUNT Search Warrant

20. Execution of the search warrant for the BARBARA VALE EMAIL ACCOUNT provided additional evidence that the VALES are continuing to sell the Enjoined Substances in violation of, among other things, the INJUNCTION. For example, on or about January 8, 2016, at approximately 2:55 p.m., BARBARA VALE, using the BARBARA VALE EMAIL ACCOUNT, wrote another individual that

Jason is doing great .. still armwrestling and keeping his business going. When one of his suppliers of B-17 (our second best seller) cut us off because we undercut their price, Jason sad [sic] "you're going to be sorry, I'm going to take over the country now" and so he made connections in China, shipped in 30K of b-17 powder, found a bottling company in California, and here we go ... took away 50% of that other company's business.

...

I am too busy .. do 3 or 4 hours of work for Jason every day.

21. On or about April 28, 2016, at 4:10 a.m., the BARBARA VALE EMAIL ACCOUNT received an email from a customer ("Customer-1") of "Vitamin B17 powder" and apricot seeds containing the following message:

Hi Barbara,

I read read [sic] some of the testimonials on the apricotsfromgod website and saw that the person who's addressed there is "Jason". If you can't help me maybe could you please forward this email to him. Yesterday I suffered severe poisoning. I only had one scoop of your b17 powder in the morning with food and then for lunch I had home made cottage cheese with 2 table spoons of flax seed oil.

Within 10 mins of eating the cheese and flax seed oil I felt terribly sick, vertigoes [sic], chills, thought I was going to pass out and then vomited everything. I was very sick the whole day and today I still feel part of the "poison" in my body.

I did a lot of research and apparently the "poisonous" cyanide molecule, or whatever it is exactly, is also present in flax seed oil and even in cow milk. So it would appear that the association of the three was like a bomb.

But even in the previous days I felt very nauseous and was knocked out for a few hours, so much so I had to go to bed. I took only one scoop of b17 powder (too much?) My mum and a friend also felt their thinking went blurred after eating the apricot kernels.

I understand you're not health practitioners, but you've been doing this long enough to know of other people who may have had the same symptoms and how they dealt with them.

Of course on the internet there are many articles stating amygdalin as a cancer cure is quackery and that it can even be lethal. I have just bought 10 bottles because I believe in this natural remedy and have read so many testimonials, but I'm a bit concerned now. ...

The BARBARA VALE EMAIL ACCOUNT did not reply to Customer-1 but, instead, forwarded the email to "jasonvale@yahoo.com."

- 22. On or about November 28, 2016, the BARBARA VALE EMAIL ACCOUNT emailed a customer located abroad and wrote "I will try to be creative in describing my next shipment (bagels maybe:) I send quite a few orders to the Netherlands and I usually say supplements and give a value of \$10 and I never insure. I haven't had any complaints yet." On December 3, 2016, the BARBARA VALE EMAIL ACCOUNT emailed the same customer and wrote "I got your order out today .. I didn't put an invoice in it ... its marked jellybeans.. They are \$50 each plus \$21 shipping... I hope it goes through customs ok...:) Love ya."
- 23. On January 29, 2019, the FDA issued a Notice of FDA Action, notifying the VALES that the FDA had detained a shipment of Apricot Kernel Extract because it "appears to be a new drug without an approved new drug application." On

February 2, 2019, JASON VALE emailed the Chinese manufacturer of the Apricot Kernel Extract, writing:

"I am very upset that you asked us to order from your company and you do not know how to ship to the United States the proper way. Also I do not understand how you can be afraid of customs. The worst that can happen is that the package gets shipped back to you. This is not an illegal product. You cannot use DHL anymore you must use FedEx or a Nother [sic] way. And you must deal with customs the minute that they contact you. ... Jason Vale www.apricotsfromgod.com

Jason Vale."

24. On February 13, 2019, the Chinese manufacturer emailed JASON VALE asking about FDA procedures, and asked, if they resent the Apricot Kernel Extract, "can we use the substitute name such as yam extract or other name instead of Apricot kernel extract?" JASON VALE replied:

"This is Jason ... Yes you can call it yam extract, baby powder, anything you like. Just email us the proper c of a and documentation. Don't use dhl please. Fed ex has never given us this problem and also don't put 7500 because the tax is much too high. We also have paid a duty tax of 700 on the last shipment with no product. Please send product and when the other batch is released we will immediately wire you the money for the second one. As of now the fda is claiming the last batch has fallen under 'New and unapproved drug. I will email you the letter that has been sent to us which the FDA says they are withholding the product."

25. Based on my review of emails, it appears that the VALES, and their employee Madeline, communicated with the FDA about the detained shipment. On February 27, 2019, the FDA emailed Madeline and JASON VALE, stating that "You need to address the concerns with importing apricot kernels indicated in the link" and providing a link to an FDA website. In pertinent part, the FDA website states that "Laetrile and amygdalin products are generally not amenable to importation under the personal

importation of drugs policy outlined in RPM Chapter 9, Subchapter 9-2 Coverage of Personal Import Importations."

26. A March 2, 2019 emails further states that:

"I just spoke with [an FDA Compliance Officer] and she said that since she just received the email from Maddie claiming the apricot seed extract is going into a body scrub she will release it today. The law only says it can't be imported from a doctor affidavit to be used with patients.

All is good.

www.apricotsfromgod.com

Jason Vale"

Based on my investigation and review of records, the VALES and their companies have never manufactured or sold any body scrub.

27. Emails received from the BARBARA VALE EMAIL ACCOUNT as recently as May 2019, indicate that the business of selling the Enjoined Substances is ongoing. For example, an email dated May 1, 2019, from the BARBARA VALE EMAIL ACCOUNT to a customer ("Customer-2") states, "We received your return today," including of apricot powder and B-17 capsules. The email represents that it will "credit [Customer-2] in the same manner it was charged," and "encourage[d] [Customer-2] to continue chewing the apricot seeds" as "[w]e have so many testimonies as to their effectiveness."

F. Surveillance

- 28. Surveillance of the 234th Street Address confirms that the VALES are operating a business selling the Enjoined Substances in part from BARBARA VALE's residence, the 234th Street Address.
- 29. On or about April 20, 2019, at 11:07 a.m., surveillance recorded JASON VALE exiting the 234th Street Address and placing packages inside a USPS bin outside of the front door for pick up by the USPS.

- 30. On or about May 7, 2019, physical surveillance depicted BARBARA VALE exiting the 234th Street Address at approximately 11:00 a.m. She placed several packages inside two USPS bins outside of the front door for pick up by the USPS (the "SUBJECT PACKAGES"). Multiple of the SUBJECT PACKAGES bore the return address, "CHRISTIAN BROTHERS, 8251 234TH STREET, BELLRS MANOR NY 11427," <u>i.e.</u>, the 234th Street Address, and contained labels with the same Click-N-Ship account number as that used in the March 1, 2019 undercover ORDER (<u>see</u> ¶ 20 <u>supra</u>).
- 31. The United States Postal Service mail carrier for the 234th Street Address states that BARBARA VALE typically sends out two to three postal tubs full of padded envelopes daily, that he picks up from the 234th Street Address. He further stated that this volume has been consistent for the two to three years that he has serviced the 234th Street Address.

REQUEST FOR SEALING

32. It is respectfully requested that this Court issue an order sealing, until further order of the Court, all papers submitted in support of this application, including the application and arrest warrant, as disclosure would give the targets of the investigation an opportunity to destroy evidence, harm or threaten witnesses, change patterns of behavior, notify confederates and flee from or evade prosecution and therefore have a significant and negative impact on the continuing investigation and may severely jeopardize its effectiveness.

WHEREFORE, your deponent respectfully requests that the defendants

JASON VALE and BARBARA VALE be dealt with according to law.

S/ Anthony Ruffini
ANTHONY P. RUFFINI
Special Agent, United States Food and Drug
Administration

Sworn to before me this 22 day of October, 2019

S/ Sankett Bulsara

THE HONORABLE SANKET J. BULSARA UNITED STATES MAGISTRATE JUDGE EASTERN DISTRICT OF NEW YORK